BioMimics 3D
The Swirling Flow® Stent

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MIMICS 3D One-Year Results

Summary

A prospective observational registry evaluating the BioMimics 3D Vascular Stent System in a real-world clinical population with a dedicated subgroup analysis of device performance as a complementary treatment in procedures involving drug-coated balloons. MIMICS-3D enrolled 507 patients across 23 clinical sites in Europe.

24% of subjects enrolled in MIMICS-3D had Critical Limb Ischemia

Baseline Patient Demographics		N=507 Subjects
Age	Mean years ± SD (N)	70.1 ± 10 (507)
Gender	% Male	65.5% (332/507)
Risk Factors	Diabetes Mellitus Smoker Current	36.9% (187/507) 37.7% (191/507)
Rutherford category	0	0.4% (2/504)
	1	1.2% (6/504)
	2	17.1% (86/504)
	3	57.3% (289/504)
	4	7.5% (38/504)
	5	14.3% (72/504)
	6	2.2% (11/504)
Ankle Brachial Index	Mean ± SD (N)	0.6 ± 0.3 (417)

38% of lesions had moderate to severe calcification

Baseline Lesion Characteristics		N=507 Subjects (518 lesions)
Reference Vessel Diameter (mm)	Mean ± SD (N)	5.3 ± 0.7
Lesion Location (%)	Mid to Distal SFA Prox. Pop	62.9% 326/518 7.3% (38/518)
Diameter Stenosis (%)	Mean ± SD	94.6 ± 8 (518)
Occlusions	Total	56.8% (294/518)
Lesion Length (mm)	Mean ± SD	127 ± 92.4
Calcification	Grade 0	17.6% (91/518)
	Grade 1	29.3% (152/518)
	Grade 2	24.1% (125/518)
	Grade 3	14.7% (76/518)
	Grade 4	13.9% (72/518)

Study Principal Investigator:
Michael Lichtenberg MD, Arnsberg, Germany

Enrolment complete:
N=507

Clinical Sites: 23 Pan European

Follow Up: 3 Years

Primary Endpoints:

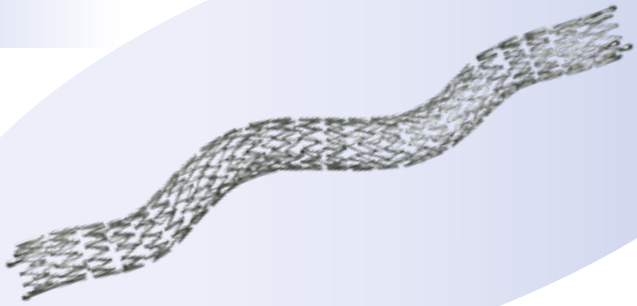
Safety – Composite of major adverse events (MAE), death, major amputation performed or CDTLR through 30 days.

Effectiveness – Freedom from clinically-driven target lesion revascularisation through 12 months.

Results

Primary Safety Endpoint: 30 days

CDTLR*	0.4% (2/490)
Major amputation target limb**	0.4% (2/491)
Death***	0.4% (2/491)
Any MAE	1.2% (6/492)



Primary Effectiveness Endpoint: 1 Year

Freedom from CDTLR

89%

DCB vs non-DCB

Subgroup analysis of device performance as a complementary treatment in procedures involving drug- coated balloons.

	BioMimics 3D *with* DCB	BioMimics 3D *without* DCB	Overall result
Freedom from CDTLR @12mo	**89.5%**	**88.5%**	**89.0%** [p > .88]

*2 events adjudicated: occulusions Day 13, 18

**2 events adudicated:

(1) Day 8, RCC 6 subject unplanned, above knee amputation; (2) Day 3, RCC 6 subject, unplanned, below knee amputation

***2 events adjudicated: (1) surgical complication following closure system failure; (2) MOF during pallitation for ALL

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Conclusions

- More challenging population than typically enrolled in registry studies:
  – 24% CLI; longer, more complex lesions; >50% with DCB.
- 12-month freedom from CDTLR: 89%.
- No statistically significant difference in 12 month CDTLR for BioMimics 3D used with or without DCB.
- **Swirling flow is nature's way of protecting patency – offering an alternative to drug elution to improve stenting outcomes.**

The MIMICS Clinical Programme: An evolving database of the safety and effectiveness of the BioMimics 3D Vascular Stent System.

Gathering clinical evidence from a "real world" patient population from single de novo to complex, long and severely calcified lesions.

1750+ patients and growing

MIMICS *FIH*	MIMICS *RCT*	MIMICS *2*	MIMICS 3D	MIMICS 3D *USA*	MIMICS *et seq*
N = 10 1 site Germany	N = 50 8 sites Germany	N = 271 43 sites USA/Japan/Germany	N = 507 23 sites Pan European	N = c. 500 c. 40 sites USA	N = c. 400 Multiple sites Europe
• First in Human • FU - 1 year • Completed	• Randomised controlled trial • FU - 2 years • Completed	• IDE Registry • FU - 3 years • Completed	• Prospective Registry • FU - 3 years • 1 year complete	• Prospective Registry • FU - 3 years • Starting 2020	• Physician initiated prospective and retrospective registries • Enrolment ongoing

MIMICS *RCT*

A randomised study comparing safety and effectiveness of the BioMimics 3D Vascular Stent System to a straight stent control. Freedom from loss of primary patency through 2 years for BioMimics 3D Vascular Stent System was superior (P = 0.05) to straight control stents (72% vs 55%). There were no stent fractures at 2 years for patients treated with the BioMimics 3D stent.[1]

MIMICS *2*

A multicentre, international (USA, Japan and Germany) IDE study. At 3 years follow-up BioMimics 3D demonstrated continuing benefit with CDTLR showing comparable outcomes to DES/DCB. Core Lab X-ray imaging review confirmed 0% stent fracture in any MIMICS-2 subject treated with BioMimics. MIMICS-2 represents a more challenging patient population. than in DES/DCB pivotal trials.[2,3]

MIMICS 3D

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MIMICS 3D *USA*

A prospective, multicentre observational study evaluating the safety, effectiveness and device performance of the BioMimics 3D Vascular Stent System within a real-world clinical population of patients undergoing femoropopliteal intervention. MIMICS-3D-USA will enrol more than 500 patients in 40 clinical sites across the United States.

1. Zeller T et al; Circ Cardiovasc Interv. 2016;9
2. Kenneth Rosenfield et al :N Engl J Med 2015;373:145-53. DOI: 10.1056/NEJMoa1406235
3. Michael D. Dake et al : Circ Cardiovasc Interv. 2011;4:495-504

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